



MEMORANDUM

Region 11 will be meeting with Region 3. Below, you will find an agenda for this meeting as well as information about the Kidney Paired Donation Meeting.

The Region 11 Meeting will be held on Friday, October 14 at the [Atlanta Marriott Suites Midtown](#) (35 14th Street NE, Atlanta, GA 30309, 404-876-8888).

The Atlanta Marriott Suites Midtown is located about two blocks from the Arts Center [MARTA](#) Station. The Arts Center MARTA Station is about 25 minutes from the Hartsfield-[Jackson Atlanta International Airport MARTA Station](#). The meeting will start with registration at 10:30 am and will be scheduled to end at 3:30 pm.

On September 16, full documentation of the proposals is available for viewing on the OPTN web site. Copies of the public comment document will be available in Atlanta.

<http://optn.transplant.hrsa.gov/policiesAndBylaws/publicComment/>

The regional meeting offers the opportunity to provide feedback on proposed policy changes, and I hope that each voting member in the region will be represented.

It is particularly important that the regional representatives for committees with public comment proposals be present to explain the proposal to the group prior to voting. Patients, their families and any other interested persons are also encouraged to attend.

The official UNOS Representative, Alternate, or a proxy designated by the Representative may have their votes recorded on issues that are considered at the meeting. If you have any question about who the voting representative is for your institution, please contact me by email Clifton.mcclenney@unos.org. Letters designating a proxy may be faxed to my attention at (804) 782-4896 or submitted at the meeting registration table.

I encourage you to get involved in UNOS through attending this upcoming regional meeting and participating in the policy making process.

There is no registration fee for the regional meeting, but attendees are responsible for covering any expenses they incur in attending.

There are a limited number of rooms available at a rate of \$189.00.. Please contact Shamel Jones- McCloud UNOS Meeting Planner (shamel.mccloud@unos.org) by September 15 to be added to the rooming list for the \$189.00 rate.

AGENDAS BELOW

AGENDA
Region 3/11 Meeting
Atlanta, GA
October 14, 2011

**All times except the start time are approximate. Actual times will be determined by the amount of discussion.*

9:30-10:30- Kidney Paired Donation (KPD) Meeting

9:30 Registration and Continental Breakfast

10:00 Welcome/Opening Remarks

George Loss, MD
Region 3 Councillor

- June 2011 OPTN/UNOS Board meeting summary
- Region 3 2012 Committee Openings
- Region 11 2012 Committee Openings

10:10 UNOS Update

Brian Shepard
UNOS Director of Policy

11:00 OPTN/UNOS Public Comment Proposals and Committee Reports

Moderator: George Loss, MD-Region 3 Councillor
Prabhakar Baliga, MD-Region 11 Councillor

Kidney Transplantation Committee –Ari Cohen, MD –Region 3 Representative/Jeffrey Rogers, MD-Region 11 Representative

Proposal to Clarify Requirements for Waiting Time Modification Requests (Kidney Transplantation Committee)

Current OPTN/UNOS policies for submitting waiting time modification requests are not clear, leading to wasted time for the transplant centers that submit requests, for OPTN Contractor staff who process requests, and for the Committees that review requests. Required documentation is often missing and results in delays for transplant candidates to receive the waiting time that they may be entitled to receive under OPTN policy. With these proposed clarifications, the Committee expects to see fewer submissions of incomplete requests and faster time to implementation of approved requests.

Liver and Intestinal Transplantation Committee-Brendan McGuire, MD-Region 3 Representative/Michael Marvin, MD-Region 1 Representative

Proposal to Extend the “Share 15” Regional Distribution Policy to “Share 15 National” (Liver and Intestinal Organ Transplantation Committee)

The Committee is proposing an extension of the current “Share 15 Regional” policy so that deceased donor livers (age 18 and higher) would be offered to all candidates with MELD/PELD scores of 15 or higher locally, regionally, and nationally before being offered to candidates with lower MELD/PELD scores.

Proposal For Regional Distribution of Livers for Critically Ill Candidates (Liver and Intestinal Organ Transplantation Committee)

This proposal would offer livers to combined local and regional candidates with MELD/PELD scores of 35 or higher (“tiered regional sharing”).

Thoracic Transplantation –TBD

Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNetSM a

Change in Criterion or Status within Twenty-Four Hours of that Change (Thoracic Organ Transplantation Committee)

The OPTN contractor's policy evaluation plan requires that heart transplant programs record in UNetSM changes to a heart transplant candidate's status or criterion within 24 hours, but this requirement is not written in Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status). The two policies state that the OPTN contractor will notify "a responsible member of the transplant team" prior to downgrading a candidate's Status, but the OPTN contractor does not notify such personnel in addition to displaying the candidate's status in UNetSM. The proposed modification includes the 24-hour requirement, removes of the notification clause, and includes edits for plain language. For consistency, the modifications also include language about potential referral of pediatric heart status exception case decisions to the Thoracic Organ Transplantation Committee.

Ad Hoc International Relations and Ethics Committees-TBD

Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions (Ad Hoc International Relations and Ethics Committees)

This proposal clarifies the data collected about the citizenship and residency of donors and recipients. The proposal also amends the audit trigger policy, allowing the Ad Hoc International Relations Committee to review the circumstances of any transplant of non-US residents/non-US citizens and make a public report. The proposal also contains technical amendments and removal of requirements that are not enforceable.

Histocompatibility Committee- Robert Bray PhD-Region 3 Representative/David Kiger CHS, CHT-Region 11 Representative

Proposed Update to the Calculated PRA (CPRA) (Histocompatibility Committee)

The purpose of this proposal is to update CPRA so it can better reflect current lab practices as well the current donor pool. These revisions include updating the HLA frequencies used to calculate CPRA, the addition of the antigen C to the calculation and the removal of zero (0) as a default value.

Revision of the UNOS Bylaws, the OPTN Bylaws and the OPTN Policies that Govern HLA Laboratories (Histocompatibility Committee)

This proposal revises the UNOS Bylaws and Policies that apply to histocompatibility laboratories to more closely align OPTN/UNOS requirements for member laboratories with current laboratory practices.

Lunch 12:15-12:45 (Provided)

Living Donor Committee –Linda Chen, MD-Region 3 Representative

Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors (Living Donor Committee)

This proposal would establish policy requirements for the informed consent of living kidney donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) and based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS); and the North American Transplant Coordinators Organization (NATCO) to the OPTN/UNOS Living Donor Committee.

Proposal To Establish Minimum Requirements for Living Kidney Donor Follow-UP (Living Donor Committee)

This proposal would require transplant programs to report required fields on the Living Donor Follow-up (LDF) form at required post-operative reporting periods (6, 12, and 24 months). The OPTN currently relies on Living Donor Follow-up (LDF) forms to collect data on the short-term health status of living donors. Data on living donors who donated in 2006 through 2009 demonstrate that many programs do not report meaningful living donor follow-up information at required reporting intervals. Consequently, to allow for meaningful analyses to objectively study the short-term effects of living donation, the transplant community must collectively improve patient information on the LDF form. The proposed minimum reporting requirements are based on recommendations from the Joint Society Work Group, which is composed of representatives from the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO) to the OPTN/UNOS Living Donor Committee.

Proposal To Establish Requirements for the Medical Evaluation of Living Kidney Donors (Living Donor Committee)

This proposal would establish policy requirements for the medical evaluation of living kidney donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA), and based on recommendations from a Joint Societies

Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS) and the North American Transplant Coordinators Organization (NATCO) to the Living Donor Committee.

Organ Procurement Organization Committee- Christy Corbitt, RN, CPTC-Region 3 Representative/Cynthia Willis-Region 11 Representative

Proposal to Eliminate the Use of an “Alternate” Label when Transporting Organs on Mechanical Preservation Machines and to Require the OPTN Distributed

Standardized Label (Organ Procurement Organization (OPO) Committee)

This proposal would make labeling of these machines consistent for all deceased and living donor organs that are transported outside of donor hospitals. Current policy allows the use of an “alternate” label, or a label other than the OPTN standardized label, when transporting organs on a mechanical preservation machine. OPOs create their own alternate labels resulting in inconsistent labeling. The proposed policy changes eliminate the use of alternate shipping labels on mechanical preservation machines and require OPOs to use a new standardized label that is part of the current color-coded labeling system distributed by the OPTN contractor.

Proposal to Change the Term “Consent” to “Authorization” Throughout Policy When Used in Reference to Organ Donation (Organ Procurement Organization (OPO) Committee)

The proposed modification will change the term “consent” to “authorization” throughout policy when used in reference to deceased organ donation. Currently, OPTN policy uses the term “consent” to describe the act of making an anatomical gift. However, the public associates “consent” with the medico-legal concept of “informed consent” through which physicians must give patients all the information they need to understand the risks, benefits, and costs of a particular medical treatment.

In the context of organ/tissue/eye donation after death, this blending of terms leads to misunderstandings about the act of donation that could hinder our national goal of increasing organ/tissue/eye donation and transplantation. The OPO community has responded to this circumstance by changing the donation terminology from “consent” to “authorization.” This change focuses attention on the altruistic act of donation and reinforces the fact that donation after death does not involve medical treatment.

Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions (Organ Procurement Organization (OPO) Committee)

The proposed policy changes clarify the definitions for determining whether a death can be classified as “imminent” or “eligible.” OPOs are responsible for reporting data that classify a death as either an Imminent Neurologic Death (“imminent,”) or Eligible Death (“eligible,”) or neither “eligible” nor “imminent” (“neither.”) The OPOs then report the “imminent” and “eligible” deaths to the OPTN. There are inconsistencies in the data reporting which have been primarily attributed to:

- OPOs interpreting the definitions in Policy 7.1 (Reporting Definitions) differently, and
- Brain death laws varying from state to state affecting the way the deaths are reported.

The Committee eliminated Multi-system organ failure as an exclusionary criteria for classifying a death as “eligible”, and identified a list of organ specific exclusionary criteria that has been added to provide more detailed guidance. The Committee also made changes to the definition of “imminent” so that it is restricted to those deaths that would most likely be classified as “eligible” had brain death been legally declared. This could allow the combination of “eligible” and “imminent” deaths to mitigate the effect

Policy Oversight Committee-TBD

Proposal to Clarify and Improve Variance Policies (Policy Oversight Committee (POC))

This proposal streamlines and clarifies requirements for review and approval of variances, including gathering all requirements into one policy category for the variance application, review, approval, modification, dissolution, and appeal processes; detailing the process for appealing a variance decision of the Committee or Board of Directors; eliminating redundancy in existing variance policies; and rewriting the variance policies using plain language.

Finance Committee –Barry Marshall, MBA, FACHE-Region 3 Representative/Donna George MS, RN, NEA-BC-Region 11 Representative

Membership & Prof. Standards Committee-Devin Eckhoff, MD-Region 3 Representative/David Shaffer, MD-Region 11 Representative

Minority Affairs –Yma Waugh-Region 3 Representative/Kelly McCants, MD-Region 11 Representative

Operations and Safety Committee –Michael Angelis, MD-Region 3 Representative/Jerita Payne, APRN, BC-Region 11 Representative

Pancreas Transplantation Committee –Joseph Magliocca, MD-Region 3 Representative/Charles Bratton, MD –Region 11 Representative

Patient Affairs –Kathleen Giery APR, CPRC Region 3 Representative/Kim Phillips RN, MSN, CCTC-Region 11 Representative

Pediatric Transplantation- Alfonso Campos, MD-Region 3 Representative/Kathy Jabs, MD-Region 11 Representative

Transplant Administrators –Leigh Ann Burgess, RN, BSN, CCTC-Region 3 Representative/Rob Teaster , RN, MBA, CPTC

Transplant Coordinators Committee – Barbara Robinson RN-Region 3 Representative/Marion Stewart RN, BSN, CCTC-Region 11 Representative

3:30 Adjournment

Kidney Paired Donation (KPD) Meeting 9:30-10:30

Also, there will be a Kidney Paired Donation (KPD) Meeting with the KPD Program Manager.

Topics that will be discussed include:

- Current status the OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP) – the manual system, what that means, and how we are doing?
- Vision and goals for the KPDPP
- Benefits of participating in the OPTN/UNOS KPDPP
- Short-term and long-term updates to the KPDPP – Moving from manual to fully automated system, what that means, and time frame for the transition
- Question to the centers: What are transplant centers looking for in a National KPD program and what can UNOS do to help centers fully participate?

Region 3 OPO/Transplant Program Roundtable (members from Region 11 are welcome to attend)

Finally for those who are flying in the day before, there will be a Region 3 OPO/Transplant Program Roundtable meeting held on October 13 from 1:00 pm to 6:00 pm. Lunch will be served at 12 noon.

The goal of the round table discussion is to address some of these issues and provide a summary to the transplant programs and OPOs in Region 3. Some of the issues to be discussed include (time permitting):

- Discuss new OPO regulations as well as Center regulations. Also, discuss Region 3 concerns, issues, or needs.
- DonorNet and provisional yes material for prelim crossmatch donor/recipient verification process
- Donor workflow, case timing, designation of high risk when not CDC high risk
- Organ allocation high-risk donor imports
- Clinical information for calls, Tiedt updates
- Management of donor, NAT testing
- Regionalization of procurement heart and lungs with great cooperation between teams
- Allocating organs from marginal donors
- How to improve organ donation?
- On call procurement teams read to depart with one hour notice to prevent organs being lost due to inability to find another transplant team in time given OR family constraints
- Current donor issues in Region 3, thoracic transplant center donor management expectations, new transplant center acceptance practices, donor management protocols and possible standardization
- Discuss O.R scheduling allocation (listing practices) communication about delays in cases
- Discuss the reasons why certain organs have better outcomes than others
- Sharing donor images, path slides electronically to distant centers, getting the organs out of the door
- Discarding of organs before notification of the OPO, arriving on time for OR issues, not sharing minimal recipient information to help comfort the donor family
- Organ declines, recurrent problems with delaying ORs
- Liver biopsy waivers which OPO's offer them, and how many of the livers that a transplant center receives on waivers are transplanted vs. discard?